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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,043	02/17/2004	William H. Fleming	6122-67949-01	8393
24197	7590	12/11/2007		
KLARQUIST SPARKMAN, LLP 121 SW SALMON STREET SUITE 1600 PORTLAND, OR 97204			EXAMINER STEPHENS, JACQUELINE F	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 12/11/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

ED

<b>Office Action Summary</b>	<b>Application No.</b> 10/781,043	<b>Applicant(s)</b> FLEMING, WILLIAM H.	
	<b>Examiner</b> Jacqueline F. Stephens	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed 9/12/07 have been fully considered but they are not persuasive. Applicant argues in light of the amendments to claims 1, 18, 31, and 44, Cox does not disclose a method for absorbing leakage comprising positioning a non-adhesive intergluteal absorbent pad external to the subject's anal orifice. Applicant further argues it would not be obvious to modify the pad of Cox who teaches a strong adhesive to adhere the pad to the body of the user. However, Cox further teaches an adhesive-free zone on the pad col. 3, lines 23-26 so that discharge from the anus is absorbed by the absorbent material of the pad. Cox further teaches a nipple portion that is adhesive free and frictionally retained between the buttocks. Thus, Cox meets the limitations of the amended claims.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-43 and 49-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Cox USPN 5695484.

As to claims 1, 2, 10-12, 18, 20, 21, 24, 25, 49, and 50, Cox discloses a method for absorbing leakage from an anus of a subject, comprising positioning an intergluteal absorbent pad external to the subject's anal orifice such that the pad is retained between the buttocks, so that discharge from the anus is absorbed by the absorbent material of the pad (col. 1, lines 40-42; col. 2, lines 15-17). Figure 4 shows the pad has a minor portion 22 superimposed on a major portion 16, which are both curvilinear in cross-section. Cox further teaches an adhesive-free zone on the pad col. 3, lines 23-26 so that discharge from the anus is absorbed by the absorbent material of the pad. Cox further teaches a nipple portion that is adhesive free and frictionally retained between the buttocks

As to claim 3, the absorbent material is a highly absorbent swellable material (col. 2, lines 14-18).

As to claims 5, 6, 13-15, 26-28, the pad has a minor portion 22 and a major portion 16 as claimed. Cox discloses the minor portion is positioned against the subject's anus (col. lines 46-50).

As to claims 7, 19, 51, and 52, Cox discloses the pad includes an agent for absorbing odors (col. 2, lines 18-22; col. 5, lines 21-30; col. 6, lines 59-61).

As to claims 8, 9, 22, and 23, Cox discloses the pad carries a therapeutically effective amount of a medicinal agent for anal delivery, where it is reasonable to conclude a subject wearing such a pad is in need of the medicinal agent (col. 2, lines 7-19).

As to claims 31, 32, and 34-41, see Figures 1-8. Cox additionally discloses the shape can be modified to achieve maximum incontinence control (col. 6, lines 23-26).

As to claim 33, Cox discloses an adhesive attachment, but the pad is held without attachment to a supporting garment.

As to claims 42 and 43, Cox discloses the pad carries a therapeutically effective amount of a medicinal agent for anal delivery, where it is reasonable to conclude a subject wearing such a pad is in need of the medicinal agent (col. 2, lines 7-19).

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox. Cox discloses the present invention substantially as claimed. Cox discloses a method for absorbing leakage from an anus of a subject comprising positioning an intergluteal absorbent pad external to the subject's anal orifice such that the pad is retained between the buttocks, so that discharge from the anus is absorbed by the absorbent material of the pad (col. 1, lines 40-42; col. 2, lines 15-17). Cox further teaches an adhesive-free zone on the pad col. 3, lines 23-26 so that discharge from the anus is absorbed by the absorbent material of the pad. Cox further teaches a nipple portion that is adhesive free and frictionally retained between the buttocks. Cox discloses a cavity 30 in the pad. However, Cox discloses an odor-absorbing agent present in the cavity rather than a medicinal agent in the cavity. Cox discloses the use of medicinal agents in various layers in the pad (col. 2, lines 7-21). It would have been an obvious design choice to one having ordinary skill in the art to incorporate a medicinal agent in the cavity since Cox teaches the general conditions of a medicinal agent in the pad layers as well as an odor-absorbing agent in the cavity.

6. Claims 16, 17, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox USPN 5695484 in view of Okuda et al. USPN 4920045. Cox does not disclose the step of performing a diagnostic test on the fecal material. Okuda discloses detection of occult blood in feces for the purpose of early finding an abnormality such as cancer or ulcer in digestion organs at an early stage (col. 4, lines 4-14). It would have been obvious to one having ordinary skill in the art to provide the

method of absorbing leakage from an anus as taught in Cox with the step of diagnostic testing of the fecal material for the benefits disclosed in Okuda.

### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline F. Stephens whose telephone number is (571) 272-4937. The examiner can normally be reached on Monday-Friday 9:00-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jacqueline F Stephens  
Primary Examiner  
Art Unit 3761

November 26, 2007